

### **REMARKS/ARGUMENTS**

Applicants acknowledge with appreciation the time and courtesies extended by the Examiner toward Applicants' representatives during recent telephone interviews. The Examiner's insights and comments have advanced the prosecution of the case.

Applicants address the Examiner's remarks in the order presented in the Office Action (dated December 12, 2003). All claim amendments are made without prejudice and do not represent an acquiescence in any ground of rejection.

### **STATUS OF THE CLAIMS**

Claims 1, 20 and 21 have been amended. Therefore, claims 1-14, 20 and 21 will be pending after entry of this amendment. Support for the amendments to claims 1, 20 and 21 can be found throughout the application as filed. For example, support can be found on page 29, at Table 2. No new matter is added by this amendment.

Claims 1-14, 20 and 21 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 15 and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meyer *et al.* (1999) in view of Ekstrand *et al.* Claim 4 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Meyer *et al.* (1999) in view of Ueno *et al.* (1995). Claims 13 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meyer *et al.* (1999) in view of Ekstrand *et al.* Claims 1-3, 5-12, 20, and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Arion *et al.* (1998) in view of Ekstrand *et al.* (1996). Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Arion *et al.* (1999) in view of Ueno *et al.* (1995). Claim 13 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Arion *et al.* (1999) in view of in view of Ekstrand *et al.* (1996), as applied *supra* to claims 1-3, 5-12, 20, and 21, and further in view of Larder *et al.* (1999a, 1999b).

### **REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claims 1-14, 20 and 21 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants have amended the claims for greater clarity and consistency of claim language. Therefore, it is submitted that this rejection has been

overcome by amendment. It is respectfully requested that the rejection of claims 1-14, 20 and 21 under 35 U.S.C. § 112, second paragraph, be withdrawn.

**REJECTIONS UNDER 35 U.S.C. § 103**

Claims 15 and 16 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Meyer *et al.* (1999) in view of Ekstrand *et al.* Claim 4 was rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Meyer *et al.* (1999) in view of Ueno *et al.* (1995). Claims 13 and 14 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Meyer *et al.* (1999) in view of Ekstrand *et al.* Claims 1-3, 5-12, 20, and 21 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Arion *et al.* (1998) in view of Ekstrand *et al.* (1996). Claim 4 was rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Arion *et al.* (1999) in view of Ueno *et al.* (1995). Claim 13 and 14 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Arion *et al.* (1999) in view of in view of Ekstrand *et al.* (1996), as applied *supra* to claims 1-3, 5-12, 20, and 21, and further in view of Larder *et al.* (1999a, 1999b).

Meyer *et al.* describe an *in vitro* assay to examine mutant activity in which they employ the HIV-1 RT mutant strains D67N / K70R / T215F / K219Q; D67N / K70R; T215F / K219Q. Arion *et al.* describe an assay with mutant strains D67N / K70R / T215F / K219Q; D67N / K70R; T215F / K219Q. Ueno *et al.* describe an assay with mutant strains A62V / V75I / F77L / F116Y / Q151M; Q151M; V75I / F77L / F116Y / Q151M; Q151M / T215Y.

Out of a large variety in number and forms of RT mutant strains that develop during the natural course of antiviral therapy, Applicants have selected specific mutant strains with various combinations of mutations, as they provide increased IC<sub>50</sub> value, or sensitivity of RT to ddNTPs. The RT strains included in the claimed assay are more efficient at extending the primer than the wild-type RT.

There are hundreds of mutant forms and combinations thereof that the RT enzyme develops under an antiviral regime. One of ordinary skill in the art would not have been motivated to select the claimed RT mutant strains without undue experimentation.

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**PATENT**  
**REPLY FILED UNDER EXPEDITED**  
**PROCEDURE PURSUANT TO**  
**37 CFR § 1.116**

In an effort to expedite prosecution of this application, Applicants have amended claims 1, 20 and 21 to the following mutants: a mutant selected from M41L / T215Y; M41L / M184V / T215Y; M41L / D67N / K70R / T215Y; M41L / D67N / K70R / M184V / T215Y; M41L / D67N / K70R / M184V / L210W / R211K / L214F / T215Y; T69S-SS; T69S-SG; T69S-AG; and T69S-SS / T215Y.

Without acceding to the propriety of the rejections of the pending claims under 35 U.S.C. § 103(a), Applicants respectfully request reconsideration of the claims as amended. For these reasons, Applicants request the Examiner to withdraw the rejections of the pending claims under 35 U.S.C. § 103(a).

#### **CONCLUSIONS**

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206.332.1380.

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